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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/592,695	06/13/2000	Andrea G Cochran	P1762R1	7146
23552	7590	10/19/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			WESSENDORF, TERESA D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/592,695

**Applicant(s)**

COCHRAN ET AL.

**Examiner**

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 August 2004 and 05 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 7-10 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-10, 14 and 20-23 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The objection to the specification and rejection under 112, second paragraph and 25 USC 102 had been obviated with the amendments to the specification and claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-10 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wrighton et al (5,830,851) for reasons advanced in the last Office action.

### ***Response to Arguments***

Applicants argue that Wrighton et al does not disclose a library of peptides comprising W at the position corresponding to M and W or L at positions corresponding to A4 of the present claims. Rather, in some embodiments, X5 of Wrighton et al., which corresponds to A2 of Applicants' claims, specifies M, F, or 1. Moreover, Wrighton et al. does not teach or suggest an isolated library or plurality of cyclic peptides with a W at position A2

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and W or L at position A4. Therefore, Wrighton et al. does not teach all of the limitations of the claims. Applicants argue that the claims are not obvious in view of Wrighton et al. because there is no suggestion or motivation, either in Wrighton et al itself or in the knowledge generally available to one of skill in the art, to modify the reference to have all limitations of the claims. The mere fact that a reference can be modified to obtain Applicants' invention does not render the claims obvious unless the prior art also suggests the desirability of the modification. MPEP 2143.01. Applicants submit that no reason has been provided why it would be desirable to modify the peptides disclosed in Wrighton et al to have all limitations of the present claims. The Wrighton et al. reference is directed to identifying agonists of EPO and identifies in certain embodiments that the position corresponding to A2 of the claimed invention is substituted with M, F or I. This reference does not teach or suggest the desirability of substituting the amino acids at this position with tryptophan. Moreover, there is no discussion in Wrighton et al. of the desirability of forming a trp-trp or trp-leu cross-strand pair between A2 and A4 in order to enhance hairpin stability. The Wrighton et al. reference does not teach or suggest the ability of the cyclic peptides as claimed by

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Applicants to accommodate a number of different types of turn structure or that the stability of the turn sequences would be enhanced.

In reply, Wrighton discloses in FIG. that a phagemid mutagenesis library; the tyrosine, glycine-proline and threonine-tryptophan residues (underlined) were fixed, as well at the two cysteines. Other positions between the cysteine residues were mutated by oligo construction such that each amino acid residue could change to any other at a frequency of 50%.

'X' denotes a random amino acid position. Accordingly, it would be within the ordinary skill in the art at the time the invention was made to use a Trp at position 2 as claimed since Wrighton discloses a trp at position two. The disclosure of Wrighton that these residues between the two cys residues are random i.e., from a library hence, it is expected that the enclosed residues would be any of the 20 naturally occurring residues including Trp. See specifically Table 8 (Seq. ID. 89) which shows a trp (W) at position A2. Thus, provided the two cys residues are fixed, as taught by Wrighton, the residues enclosed therein can be varied or substituted by a random residue from a library of residues. The disclosure of Wrighton of replacing the amino acid with a library would provide the motivation to one skill in the art to make the modification. It is well known in

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the art that a library containing all the 20 natural residues including trp facilitates identification of lead compounds by using high throughput screening to screen the library.

Applicants' further arguments that Wrighton is directed to identifying EPO agonist is immaterial, as Wrighton discloses or suggests the claimed compound. The argued enhanced stability or turns would be a property that would be considered inherent to the compound of Wrighton since the compound is similar, as claimed. Furthermore, applicants' arguments are not commensurate in scope with the claims. The claims do not recite the argued increased stability. Nevertheless, it would be within the ordinary skill in the art to determine such property given a known peptide sequence using known techniques as stated in the specification.

The rejection of claims 1-3, 5-10, 12-14 and 20-22 under 35 U.S.C. 103(a) as being unpatentable over McLafferty et al (Gene) is moot with the amendments and cancellation of some claims.

#### **Conclusion**

Claims 11 and 12 are free of prior art and would be allowable when incorporated into claim 1 with the term "consisting essentially of" the claimed sequence.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw

October 18, 2004